

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration for Children and Families****Submission for OMB Review; Comment Request**

*Title:* Objective Work Plan (OWP), Objective Progress Report (OPR) and Project Abstract.

*OMB No.:* 0980-0204.

*Description:* Content changes are being made to the OPR only. The information in the OPR is being collected on a quarterly basis to monitor the performance of grantees and better gauge grantee progress. The standardized format will allow ANA to report results across all its program areas and flag grantees that may need additional training and/or technical assistance to successfully implement their projects.

Following are content changes being made within specific sections of the OPR form:

*Objective Work Plan Update Section:* Adding 1st through 4th Quarter (Q1,Q2,Q3,Q4) results for Activities within each Objective. The grantee can continue to add to this form each quarter (rather than on to a new form), reflecting cumulative results throughout the project period rather than just the quarter.

*Financial Section:* Add 2 Questions: (1) Provide details on any income generated as a result of ANA project activities; (2) Provide details on any changes made to the budget during the reporting period.

*Native American Youth and Elder Opportunities Section:* Add Question: (1) Request details on any intergenerational activities between grandparents and their grandchildren.

Finally, add a new section (last section) to the form:

*Project Sustainability:* (1) Request details on the grantee's intention to

continue the project benefits and/or services after the project period has ended.

End of Content Changes to the OPR.

No changes are being made to the OWP or to the Project Abstract (below).

The information collected by the OWP is needed to properly administer and monitor the Administration for Native Americans (ANA) programs within the Administration for Children and Families (ACF). The OWP assists applicants in describing their projects' objectives and activities, and also assists independent panel reviewers, ANA staff and the ANA Commissioner during the review and funding decision process.

The Project Abstract provides crucial information in a concise format that is utilized by applicants, independent reviewers, ANA staff and the ANA Commissioner.

*Respondents:* Tribal Government, Native non-profit organizations, Tribal Colleges & Universities

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OWP .....	500	1	3	1,500
OPR .....	275	4	1	1,100
Project Abstract .....	500	1	0.50	250

Estimated Total Annual Burden Hours: 2,850.

**Additional Information**

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

**OMB Comment**

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202-395-6974, Attn: Desk Officer for the

Administration for Children and Families.

Dated: March 6, 2009.

**Janean Chambers,**

*Reports Clearance Officer.*

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**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2007-E-0228]

**Determination of Regulatory Review Period for Purposes of Patent Extension; PROFENDER**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for PROFENDER and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the

Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

**ADDRESSES:** Submit written comments and petitions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a